



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: Box ISSUE FEE
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

18N1/1129

DANN, DORFMAN, HERRELL & SKILLMAN
SUITE 720
1601 MARKET STREET
PHILADELPHIA, PA 19103-2307

**NOTICE OF ALLOWANCE
AND ISSUE FEE DUE**

☐ Note attached communication from the Examiner

☐ This notice is issued in view of applicant's communication filed _____

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
07/984,264	12/01/92	017	WOODWARD, M 1813	11/29/94
First Named Applicant: EKINS, ROGER P.				

TITLE OF INVENTION: DETERMINATION OF AMBIENT CONCENTRATION OF SEVERAL ANALYTES

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1	S142	436-518.000	G65	UTILITY	YES	\$605.00	02/28/95

THE APPLICATION IDENTIFIES ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY Status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
- B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.

III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
---------------	-------------	-----------------------	---------------------

07/984,264 12/01/92 EKINS

R 5142

EXAMINER
WOODWARD, M

18N1/1129
DANN, DORFMAN, HERRELL & SKILLMAN
SUITE 720
1601 MARKET STREET
PHILADELPHIA, PA 19103-2307

ART UNIT	PAPER NUMBER
----------	--------------

1813

21

DATE MAILED: 11/29/94

NOTICE OF ALLOWABILITY

PART I

- (9/15/94)
1. ☒ This communication is responsive to Req. for Reex (8/26/94) & EKINS Decl. (8/26/94)
2. ☒ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
3. ☒ The allowed claims are 12-28
4. ☒ The drawings filed on 2/21/90 are acceptable.
5. ☒ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received. [] not been received. [] been filed in parent application Serial No. PGT/GB88/0049 filed on 8/5/88
6. ☐ Note the attached Examiner's Amendment.
7. ☐ Note the attached Examiner Interview Summary Record, PTOL-413.
8. ☒ Note the attached Examiner's Statement of Reasons for Allowance.
9. ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
10. ☐ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
2. ☐ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
- a. ☐ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. . CORRECTION IS REQUIRED.
- b. ☐ The proposed drawing correction filed on has been approved by the examiner. CORRECTION IS REQUIRED.
- c. ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
- d. ☐ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- Examiner's Amendment
- Examiner Interview Summary Record, PTOL-413
- ☒ Reasons for Allowance
- Notice of References Cited, PTO-892
- Information Disclosure Citation, PTO-1449
- Notice of Informal Application, PTO-152
- Notice re Patent Drawings, PTO-948
- Listing of Bonded Draftsmen
- Other

The following is an Examiner's Statement of Reasons for Allowance:

The examiner has considered applicant's arguments in the amendment of August 22, 1994 in conjunction with the Ekins declaration and the letter of Wagner.

5 The Ekins Declaration under 37 C.F.R. § 1.132 filed August 26, 1994 presents four lines of argument directed to establishing that the teachings of Ekins '264 and Leaback '807 would not have lead one of ordinary skill in the art to assays employing less than 0.1 V/K moles of binding agent.

10 Ekins asserts that "before the present invention, no-one realized the importance of using less than 0.1 V/K moles of binding agent" and in particular that he was unaware of the importance of less than 0.1 V/K at the time the invention of '246 was made. But this line of argument ignores the teachings of Ekins '246 that the choice of the amount of binding agent to employ in the assay is such that it will not significantly effect the concentration of free analyte and that the value set forth in the example must be regarded as an upper limit. It is clear that lesser amounts of binding agent would lead to even less significant depletion of
15 analyte from solution. One of ordinary skill in the art at the time the invention was made would have constructed the plots of Figure 1 of the instant application in confirming the theoretical validity of Ekins '246.

20 Ekins further asserts that (1) "there was a clear prejudice amongst those skilled in the art against even trying to reduce the amount of binding agent used in assays," (2) "there is no suggestion in the above-noted citations that assays using such small amounts of binding agent could be as or more sensitive than conventional assays" and (3) "there existed a clear prejudice against the use of small amounts of binding agent on the grounds that such use reduced the rate of the reaction between binding agent and analyte, thus prolonging the time required to reach the degree of analyte binding regarded as necessary for the achievement of
25 acceptable sensitivity."

The refusal of the art to consider the teachings of Ekins '246 which is what point (2) concerns does not provide evidence of non-obviousness.

30 Whether or not the art had a prejudice concerning reaction rates (4) while of interest is not persuasive of non-obviousness because the specification does not establish that the instant invention has reaction kinetics that are different than the assays of the prior art.

Assertion (3) indirectly speaks to the central issue which is: given the teachings of '246 would one of ordinary skill in the art have recognized the necessity for localizing the binding reagent in small spots of high binding agent density in order to arrive at an assay with acceptable sensitivity.

5 Upon reconsideration of Ekins '264 the examiner does not find therein a suggestion to localize the binding reagent in a small spot of high binding agent density. Leaback is similarly lacking in such a suggestion as is the prior art. It is because there is no suggestion to localize the binding reagent in a small spot of high binding agent density and in which the 0.1 V/K condition is met that the invention is non-obvious and the instant claims are
10 allowable.


 Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Woodward whose telephone number is (703) 308-3890.

 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

20 Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

 The CM1 Fax Center number is (703) 305-3014.

25

CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180

November 27, 1994